SEP - 8 2006

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Kalamazoo, MI 49001
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stryker
Instruments

K061835

510(k) Summary

Device Sponsor:	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001 (p) 269-323-7700 (f) 269-324-5412
Registration No.:	1811755
Trade Name:	Stryker Silverglide Bipolar Forceps Reusable Cable Stryker Silverglide Bipolar Forceps Disposable Cable
Common Name:	Electrosurgical cutting and coagulation device and accessories
Classification Name:	Bipolar Forceps Cable
Equivalent to:	K042608 Techno Instruments (Pvt) Ltd. Reusable Bipolar Forceps Cable K023996 Modern Medical Equipment Mfg. Ltd. Disposable Bipolar Forceps Cable
Device Description:	The Stryker Silverglide Bipolar Forceps Reusable Cable is an electrosurgical accessory designed to transfer electrosurgical power to bipolar forceps from an electrosurgical generator. The cable is designed to fit standard bipolar forceps and generator connectors. The Silverglide Surgical Bipolar Forceps Reusable Cable is supplied non-sterile. It must be steam sterilized before use. The Stryker Silverglide Bipolar Forceps Disposable Cable is an electrosurgical accessory designed to transfer electrosurgical power to bipolar forceps from an electrosurgical generator. The cable is designed to fit standard bipolar forceps and generator connectors. The Silverglide Surgical Bipolar Forceps Disposable Cables is supplied sterile, and is a single-patient use device.
Indications for Use:	The Stryker Silverglide Bipolar Forceps Reusable Cable and Stryker Silverglide Bipolar Forceps Disposable Cable are intended to transfer electrosurgical power to bipolar forceps from an electrosurgical generator.
Contraindications:	None

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Substantial Equivalence (SE) Rational:

The Stryker Silverglide Bipolar Forceps Reusable Cable and the Stryker Silverglide Bipolar Forceps Disposable Cable have the same intended use as the **Techno Instruments (Pvt) Ltd. Reusable Bipolar Forceps Cable** and the **Modern Medical Equipment Mfg. Ltd. Disposable Bipolar Forceps Cable**. This device and the predicate device have the same technological characteristics, the same operating principles and have similar performance characteristics.

Safety and Effectiveness:

Based upon the comparison to the predicate devices, the Stryker Silverglide Bipolar Forceps Reusable Cable and the Stryker Silverglide Bipolar Forceps Disposable Cable are substantially equivalent to legally marketed devices.

Submitted by:

Jean Sheppard
Regulatory Analyst

_____
Signature

Date submitted: _____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2006

Stryker Instruments
% Ms. Jean W. Sheppard
Regulatory Analyst
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Re: K061835
Trade/Device Name: Stryker Silverglide Bipolar Forceps Reusable Cable and
Stryker Silverglide Biopolar forceps Disposable Cable
Regulatory Number: 21 CFR 878.4400
Regulatory Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 28, 2006
Received: June 29, 2006

Dear Ms. Sheppard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

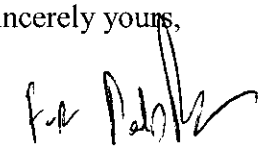
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(K) Number (if known): K061835

Device Name: Stryker Silverglide Bipolar Forceps Reusable Cable and Stryker Silverglide Bipolar Forceps Disposable Cable

Indications for Use:

The Stryker Silverglide Bipolar Forceps Reusable Cable and Stryker Silverglide Bipolar Forceps Disposable Cable are intended to transfer electrosurgical power to bipolar forceps from an electrosurgical generator.

Prescription Use X or Over-The-Counter Use _____
(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K061835